REMARKS

Claims 1-24 remain in this application. Claim 17 is amended; claim 21 is cancelled; and claim 24 has been added. Applicants thank the Examiner for the indication that claims 1-16 are in condition for allowance.

The Examiner rejected claims 17, 20 and 21 under 35 U.S.C. § 112 as lacking proper antecedent basis for "return lumen". Applicants have amended claim 17 to add the proper antecedent basis, and therefore request that the rejection be withdrawn.

The Examiner rejected claim 17 under 35 U.S.C. § 102(a) as being anticipated by Lary (U.S. Patent No. 4,237,128). The Examiner states that Lary contains a lumen capable of having blood flowing therethrough. The Examiner further rejected claims 18-23 under 35 U.S.C. §103(a) as being unpatentable over Lary in view of Lee (U.S. Patent No. 5,125,904). Applicants respectfully traverse these rejections.

Applicants have amended claim 17 to clearly distinguish Lary from the claimed invention by incorporating claim elements from claim 22. Independent claim 17 claims a cardiopulmonary bypass catheter system that includes a cannula having a return lumen that has a return outlet and is adapted for flowing blood therethrough, and an occlusion catheter sized and configured to be slidably positioned through the return lumen. The occlusion catheter has an occlusion member that has a collapsed configuration adapted for introduction through the return lumen and an expanded configuration adapted for occlusion of the ascending aorta between the coronary ostia and the brachiocephalic artery. Finally, the return lumen is configured to deliver blood via the return outlet at a flow rate sufficient to maintain arterial circulation with the heart arrested when the occlusion catheter is positioned therein.

Applicants respectfully submit that neither Lary nor Lee teach or suggest the claimed invention either alone or in combination. The system described in Lary does not include a cannula having a lumen adapted for flowing blood therethrough. Further, Lary does not describe a return lumen that is configured to deliver blood via the return outlet at a flow rate sufficient to maintain arterial circulation with the heart arrested when at least a portion of the occlusion catheter is positioned therein.

In contrast, Lary describes a relatively typical balloon angioplasty system that includes a cannula 12 that may be passed through a peripherally introduced catheter 23,

where the cannula has a balloon 16 disposed about a distal portion. See Figures 1 and 10. The cannula is sized such that the balloon reaches a coronary artery so the balloon may be used in a conventional angioplasty procedure. See col 3:60-col 4:10. That is, the balloon is located at an existing constriction within a coronary artery and expanded to spread the stenosis within the coronary artery. The catheter 23 of Lary communicates with syringe 20a, which is used to inflate balloon 16, and syringe 20b, which is used to introduce medical fluid, presumably via the same lumen within catheter 23 as that used to house the balloon cannula 10. There is no discussion in Lary regarding the size of catheter 23 lumen used to house the balloon cannula, nor does Lary discuss the amount of flow of any medical fluid passed through the catheter via syringe 20b.

Importantly, Lary does not discuss using its catheter and cannula system for use with a bypass procedure, and as a result, do not teach or suggest providing a cannula configured to deliver blood to a return outlet in amounts sufficient to maintain arterial circulation when the heart arrested. Lary does not teach each of the claimed elements of claim 17, and therefore, Applicants request that the Examiner withdraw the rejection.

The Examiner also rejected claims 18-23 under 35 U.S.C. § 103(a) as obvious over Lary in view of Lee (U.S. Patent No. 5,125,904). Applicants respectfully traverse this rejection.

The Examiner has cited Lee for the proposition that Lee "teaches the use of a hemostasis valve with a catheter". This teaching is potentially relevant to claim 18, which claims a hemostasis valve. And, as to claim 18, Applicants submit that claim 18 and each of the claims that depend from claim 17 are novel at least because they are dependent on novel claim 17.

But as to the remaining pending claims, Lee is not relevant to the elements taught in claims 19 (where the occlusion catheter has an infusion lumen having an infusion outlet located distal to the occlusion member); claim 20 (wherein the return lumen has an inner diameter of about 5-9 mm); claim 22 (wherein the occlusion catheter is sized such that the occlusion member is located within the ascending aorta between the coronary ostia and the brachiocephalic artery, when the cannula is introduced into an artery peripheral to the aorta; or claim 23 (wherein the occlusion member is configured to occlude the aorta when the occlusion member is in the expanded configuration). The Examiner has met his burden to

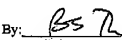
describe how Lee in combination with Lary renders claims 19, 20, 22 and 23 obvious. Applicants submit that claims 18-21 and 23 are novel over the Lee combination with Lary and request the Examiner to withdraw the rejection to claims 18-20 and 22-23.

Further, Applicants submit that new claim 24 is novel as neither Lary nor Lee teach or describe a cardiopulmonary bypass catheter system that includes: a) an occlusion catheter having an occlusion member that has a collapsed configuration adapted for introduction through the return lumen and an expanded configuration adapted for occlusion of the ascending aorta between the coronary ostia and the brachiocephalic artery; and b) a cannula having means for delivering blood at a flow rate sufficient to maintain arterial circulation when the heart arrested when at least a portion of the occlusion catheter is disposed within the means; and wherein the occlusion catheter is sized and configured to be slidably positioned through the means.

Applicants submit a petition for a one-month extension of time and grant the Commissioner permission to charge Deposit Account No. 10-0750/HRT0023/BST, as may be required, in connection with the prosecution of this application. Applicants also submit a fee sheet granting the Commissioner permission to charge the above account for the fee due for adding the additional claims.

In view of the above, Applicants respectfully submit that the application is in condition for allowance. If the Examiner believes that a telephone conference with Applicants' agent would advance the prosecution of this case, the Examiner is requested to telephone the undersigned.

Respectfully submitted,

By: 
Brian S. Tomko
Reg. No. 41,349

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-1239
(732) 524-5575 (fax)
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